

APR 11 2013

5.0 510(k) Summary



In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Mentor® CPX™4 Breast Tissue Expanders and Mentor® CPX™4 With Suture Tabs Breast Tissue Expanders device is provided below.

Device Common Name: Expander, Skin, Inflatable

Device Proprietary Name: Mentor® CPX™4 Breast Tissue Expanders and Mentor® CPX™4 with Suture Tabs Breast Tissue Expanders

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Date Prepared: March 21, 2013

Classification

Regulation: Unclassified, Pre-Amendment

Panel: General & Plastic Surgery

Product Code: LCJ

Predicate Device: K011500, Mentor Contour Profile Tissue Expander

Indication for Use:

The Contour Profile Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

Device Description:

The CPX™4 Tissue Expanders are used for breast reconstruction following mastectomy and are intended for temporary subcutaneous or submuscular implantation and are not intended for use beyond six months.

In order to provide these tissue expanders with elasticity and integrity, the shells are made with successive cross-linked layers of silicone elastomer. Superior and anterior reinforcement allows for directional expansion in the lower pole of the devices. The devices have integral, silicone elastomer, magnetically detected, injection ports and incorporate a BUFFERZONE® area with self-sealing technology that is attached to the inside of the anterior surface of the

device to minimize and/or prevent leakage in the event of an accidental needle puncture. The textured shell provides a disruptive surface for collagen interface.

Identification of the injection port site is accomplished by use of the CENTERSCOPE® Magnetic Injection Port Locator, which is provided with the Tissue Expander. Injections into the injection dome area are made using the provided infusion needle set to inject sterile, pyrogen-free Sodium Chloride U.S.P. Solution.

Suture fixation tabs are incorporated into some models of the MENTOR® CPX™4 Tissue Expanders to give surgeons the option to attach the device to surrounding tissue for enhanced device stability. Surgeons can suture on any part of the tab surface or the suturing hole can be used for added convenience.

Technological Characteristics:

The proposed modifications to the already cleared Contour Profile Tissue Expander include minor configuration changes to make the device more pliable, minor dimensional changes, and a modified magnet component. No new technological characteristics were introduced as a result of the proposed modifications.

Performance Data:

Non-clinical performance testing was conducted in order to demonstrate substantial equivalence with the predicate device. This testing was performed as required by the risk analysis and in accordance with design control procedures. The testing that was performed evaluated parameters related to joint strength, leak performance and other device performance parameters.

All non-clinical performance testing results met their pre-determined acceptance criteria, thus demonstrating that the modified device performs as well as or better than the predicate device.

Substantial Equivalence:

This 510(k) describes minor changes to the design of the Mentor Contour Profile Tissue Expander. There have been no changes to the indications for use or the intended use. The changes do not raise different questions of safety or effectiveness and results of non-clinical performance evaluations demonstrate that the proposed device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

MENTOR Worldwide LLC
% Mr. Martin Sprunck
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April 11, 2013

Re: K130813

Trade/Device Name: Mentor® CPX™4 Breast Tissue Expanders and
Mentor®CPX™4 with Suture Tabs Breast Tissue Expanders

Regulatory Class: Unclassified

Product Code: LCJ

Dated: March 21, 2013

Received: March 25, 2013

Dear Mr. Sprunck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K130813

Device Name:

Mentor® CPX™4 Breast Tissue Expanders and Mentor® CPX™4 with Suture Tabs Breast Tissue Expanders

Indications For Use:

The Contour Profile Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)

Division of Surgical Devices

510(k) Number: K130813